DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

g1145d

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

April 17, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01 – 53

Boaz Avitall, M.D., Ph.D.
Chairman of the Board and
Chief Technical Officer
AvidCare Corporation
152 W. Wisconsin Avenue
Milwaukee, Wisconsin 53203

Dear Dr. Avitall:

We are writing to you because on September 12-29, 2000, investigators from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the Home Health Monitoring Systems (including the Clinical Monitoring Station) that you manufacture.

Under a United States Federal law, the Federal Food, Drug and Cosmetic Act (the Act), these products are considered to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. Home Health Monitoring Systems and their associated software are medical devices as defined by Section 201(h) of the Act.

Your firm is manufacturing and marketing a Model SP-20 Asthma Monitoring System which uses spirometry for in-home monitoring of asthma. That device does not have a 510(k) pre-market clearance or pre-market approval.

During the September 12-29, 2000, inspection you claimed to be exempt from pre-market requirements because the device is the subject of an investigational study conducted by [redacted] and [redacted] Based on the information provided to our investigators during the inspection, it did not appear that this study formed a valid basis for exemption because the requirements for Investigational Device Exemptions (Title 21, Code of Federal Regulations, Part 812 [21 CFR 812]) have not been met. Investigations conducted at [redacted] and [redacted]

verified that the SP-20 Asthma Monitoring System is not exempt from pre-market requirements.

Therefore, the Model SP-20 Asthma Monitoring System (including the home monitor, clinical station and associated software) is adulterated within the meaning of Section 501(f)(1)(B) of the Act in that they are Class III devices under Section 513(f) and do not have an approved application for pre-market approval in effect pursuant to Section 515(a) or an approved application for an Investigational Device Exemption under Section 520(g).

The SP-20 Asthma Monitoring system is also misbranded within the meaning of Section 502(o) of the Act in that a notice or other information respecting the modification and new intended use of the device was not provided to the FDA as required by Section 510(k) and 21 CFR 807.81(a)(3)(i) and (ii).

Our inspection also found that your devices are adulterated within the meaning of Section 501(h) of the Act in that the methods used in, facilities or controls used for manufacturing, packing, storage or installation of the medical devices are not in conformance with the Good Manufacturing Practices (GMP) requirements set forth in the Quality System Regulations for Medical Devices as prescribed by 21 CFR 820.

GMP violations that were observed during the September 12-29, 2000, inspection include:

1. Failure to establish and maintain procedures to control the design of the device in order to ensure that specified requirements are met (21 CFR 820.30). For example, software version 1.18 was not implemented through an Engineering Change Order, and the software was not validated.

2. Failure to establish and maintain procedures for implementing corrective and preventive action (21 CFR 820.100). For example, a recall was conducted without following established procedures.

3. Failure to maintain a complete Device Master Record (21 CFR 820.181). For example, the Remote Programming Function is not included in the functional requirement specifications.

4. Failure to develop, conduct, control and monitor production processes to ensure that devices conform to specifications (21 CFR 820.70). There is no procedure to define and control the use of remote programming.

5. Failure to conduct quality audits to assure that the quality system is in compliance with requirements (21 CFR 820.22). There are no records that quality audits have been conducted.

6. Failure to establish and maintain procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed (21 CFR 820.160). Packing lists and shipping documents erroneously indicate that products have been shipped when, in fact, they have not been shipped.

7. Failure to establish and maintain procedures to control labeling (21 CFR 820.120). No written procedures exist to assure that only properly released labeling is shipped with devices.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. As the most responsible individual at AvidCare, it is ultimately your responsibility to ensure that devices manufactured at your facility in Milwaukee, WI, are in compliance with each requirement of the Act and regulations.

The specific violations noted in this letter and in the form FDA-483 issued at the close-out of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems you must promptly initiate permanent corrective actions.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts. Additionally, no pending applications for pre-market approval (PMAs) or export approval requests will be approved and no pre-market notifications [Section 510(k)'s] will be found to be substantially equivalent for products manufactured for your facility until the violations have been corrected.

We received Edward Paulsen's letter dated October 18, 2000, responding to the form FDA-483 issued on September 29, 2000. Your firm's response to the form FDA-483 appears to be adequate. However, a follow-up inspection will be conducted to verify that the procedures, documentation and training you have proposed have been effectively implemented.

Please let this office know in writing within 15 working days from the date you received this letter what steps you are taking to correct the adulteration [501(f)(1)(B)] and misbranding [502(o)] charges regarding the Model SP-20 Asthma Monitoring system. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Compliance Officer Timothy G. Philips at the address indicated on the letterhead.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-800-638-2041 or through the Internet at *http://www.fda.gov.*

If you have more specific questions about how FDA marketing requirements affect your particular device or about the content of this letter please feel free to contact Mr. Philips at (612) 334-4100 ext. 192.

Sincerely,

James A. Rahto
Director
Minneapolis District

TGP/ccl
Enclosure: FDA-483, 9/29/00